

**REMARKS**

Appreciation is hereby expressed to Examiner Diramio for the interview so courteously granted on October 9, 2008. Pursuant to that interview, independent Claim 6 has been amended to require that the plasma or serum separating membrane have a porosity of not more than 25%. Support for this amendment can be found in the Specification on page 8, lines 23-25. In addition, Claim 6 has further been amended to require that the plasma or serum separating membrane have a mean surface roughness of not more than 100 nm. Support for this amendment of Claim 6 can be found in the specification on page 10, lines 11-15. The present amendment is deemed not to introduce new matter. Claims 6-8, 11-15, and 17-20 remain in the application.

Reconsideration is respectfully requested of the rejection of Claims 6-8, 14, 15, 18, and 19 under 35 U.S.C. 103(a) as being unpatentably obvious over Kitajima, et al., in view of Kadoya and Matsuda, et al.

As the Examiner recognizes, the primary reference of Kitajima, et al. fail to teach that the first filter member has a packing density of a downstream part higher than a packing density of an upstream part in the filter member, or that the miroporous (plasma or serum separating) membrane has a porosity of not more than 30%.

In order to cure these deficiencies in the primary reference of Kitajima, et al., the Examiner relies upon the secondary references of Matsuda, et al. and Kadoya.

In an effort to cure the deficiencies of Kitajima, et al. discussed above, the Examiner relies upon the secondary reference of Kadoya which is concerned with a multi-layer filter medium of a non-woven fabric of a lower fiber density laminated to a filter paper of a higher fiber density. The multi-layer filter medium of Kadoya is designed for use as an oil filter or air

filter for an internal combustion engine. There is no suggestion in Kadoya that the multi-layer filter medium could be used for the separation of plasma or serum components from blood without causing breakage of erythrocytes.

In particular, Kadoya discloses that relatively large particles are trapped by the upstream non-woven fabric to promote the formation of a dust cake layer on the surface of the filter paper. The surface trapping may prevent the particles from being embedded within the filter medium, thus preventing the filter medium from being clogged therein (column2, lines 14-24). Further, the filter of Kadoya was developed for preventing clogging of the filter by dust particles, and thus the feature of the present invention, i.e., increasing the difference between moving speeds of the plasma and serum and corpuscles in blood cannot be found in the secondary reference.

It is clear from the above that the Kadoya patent is non-analogous art with respect to the problem the present inventors sought to solve which is to provide a filter apparatus to separate serum or plasma components from corpuscles in blood without causing hemolysis.

There is no teaching or suggestion in either of the Examiner's primary or principal references that they can be combined in the manner suggested in the rejection. In this same connection, the problems being solved were different, and the material being filtered was different. Further, there is no disclosure in Kadoya of employing with the multi-layer filter medium a plasma or serum separating membrane for separating plasma or serum from blood, with the separating membrane having a porosity of not more than 25% and being serially connected in a subsequent stage with the first filter member. Further, there is no motivation to combine the oil filter for a combustion engine of Kadoya with the blood separation apparatus of Kitajima, et al. since the problem being solved is different, and the solution to that problem is

different.

In view of the foregoing, it is strongly urged that it would not be obvious to combine the references in the manner suggested by the Examiner because these references are concerned with entirely different arts, i.e., filtering blood in the case of Kitajima, et al., and filtering either oil or air for an internal combustion engine in the case of Kadoya. Moreover, even if these references were combined in the manner suggested by the Examiner, there is still no teaching or suggestion of employing in the filter medium a plasma or serum separating membrane for separating plasma and serum from blood with the separating membrane having a porosity of not more than 25%, and being serially connected in a subsequent stage to the first filter medium. On the contrary, this teaching or suggestion comes only from the present application, and constitutes an important element or aspect of the invention.

As for Matsuda, et al. relied upon by the Examiner as a secondary reference, independent Claim 6 is amended to patentably distinguish from the references of record. During the interview held on October 9, 2008, the undersigned discussed Matsuda, et al. and the fact that it only taught a single filter membrane, and that Matsuda, et al. provides a teaching of and motivation for a porosity of a membrane that is between 30 – 80%.

In particular, Matsuda, et al. teaches in column 3, lines 43-50, that:

“When the porosity of a porous membrane is less than 30%, the porous membrane is too low in water permeability to be useful as a fine microfilter though it possesses an excellent mechanical strength and elongation.”

It was therefore urged during the interview that in view of the above quoted disclosure of Matsuda, et al., this secondary reference teaches away from the use of a porous membrane having

a porosity of 25% as now called for in Claim 6. Further, it is respectfully urged that there is no disclosure in any of the references of record of using a plasma or serum separating membrane having a mean surface roughness of not more than 100 nm, as now required by amended Claim 6 herein.

It is respectfully submitted that none of the references of record disclose a filter apparatus as now called for in the claims herein. It is also respectfully submitted that the amended claims herein patentably distinguish from the Examiner's combination of references, taken individually or in combination. Consequently, the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claims 11 and 20 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al. in view of Kadoya and Matsuda, et al. as applied to Claim 6, and further in view of Ayres.

The deficiencies of Kitajima, et al., Kadoya, and Matsuda, et al. are discussed above.

The Examiner's secondary reference of Ayres fails to cure the deficiencies of Kitajima, et al., Kadoya, and Matsuda, et al. because there is no disclosure whatever in Ayres of a filter apparatus having a plasma or serum separating membrane with a porosity of not more than 25% and a mean surface roughness of not more than 100 nm. The surface roughness is particularly important since the specification herein on page 10, lines 11-15, teaches that if the mean surface roughness exceeds 100 nm, the load applied on erythrocytes becomes large and hemolysis is more likely to occur.

For these reasons, it is respectfully submitted that dependent Claims 11 and 20, incorporating the limitations of Claim 6, patentably distinguish from the references of record for

the reasons set forth above.

Reconsideration is respectfully requested of the rejection of Claim 12 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al., in view of Kadoya, and Matsuda, et al., as applied to Claim 6, and further in view of Bell.

The deficiencies of the Kitajima, et al., Kadoya and Matsuda, et al. references are discussed above with respect to independent Claim 6. Claim 12 which is dependent upon Claim 6 requires the same limitations as Claim 6. However, the Bell reference fails to cure the deficiencies of the other references. This is especially true with respect to the porosity and mean surface roughness of the plasma or serum separating membrane as now required by amended Claim 6. Consequently, since none of the references of record meet the limitations of the claims as amended, it is respectfully submitted that the claims now in the application patentably distinguish from the prior art of record. For these reasons, it is believed that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

Reconsideration is respectfully requested of the rejection of Claim 13 under 35 U.S.C. 103(a) as being unpatentable over Kitajima, et al., in view of Kadoya, and Matsuda, et al. as applied to Claim 6, and further in view of Anraku.

The deficiencies of Kitajima, et al., Kadoya, and Matsuda, et al. are discussed above.

The Anraku reference fails to cure the deficiencies of the other references discussed above, and, in particular, Anraku fails to disclose a filter apparatus having a plasma or serum separating membrane with a porosity of not more than 25%, and a mean surface roughness of not more than 100 nm. On the contrary, that teaching or suggestion comes only from the present

application and constitutes an important element or aspect of the present invention. Failing a disclosure of these requirements of amended Claim 6, it is respectfully submitted that dependent Claim 13 is neither anticipated by nor unpatentably obvious over the Examiner's combination of references. Withdrawal of the rejection is accordingly respectfully requested.

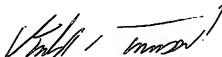
Reconsideration is respectfully requested of the rejection of Claim 17 under 3 U.S.C. 103(a) as being unpatentable over Kitajima, et al., in view of Kadoya, and Matsuda, et al., as applied to Claim 6, and further in view of Chu.

The deficiencies of Kitajima, et al., Kadoya, and Matsuda, et al. are discussed above.

The Chu reference fails to cure the deficiencies of the other references discussed above, and, in particular, Chu fails to disclose a filter apparatus having a plasma or serum separating membrane with a porosity of not more than 25% and a mean surface roughness of not more than 100 nm. For these reasons, it is respectfully submitted that the Examiner's combination of references fail to anticipate or render unpatentably obvious the subject matter now called for in the claims herein. It is therefore believed that the Examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is now in condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,



Donald E. Townsend  
Reg. No. 22,069

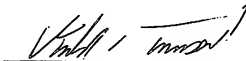
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TOWNSEND & BANTA  
c/o PortfolioIP  
P.O. Box 52050  
Minneapolis, MN 55402  
(202) 220-3124

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**CERTIFICATE OF TRANSMISSION**

I hereby certify that this transmission, consisting of a 13-page Amendment in U.S. patent application serial No. 10/533,539, filed on May 2, 2005, is being electronically transmitted to the U.S. Patent and Trademark Office via EFS on October 28, 2008.



Donald E. Townsend